Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the results of scaphoid waist fracture fixation using screws and screws with pins in acute scaphoid waist fractures

Protocol summary

Study aim

1. Comparison of scaphoid waist fracture fixation using a screw alone versus screw combined with pin fixation in acute scaphoid waist fractures based on the degree of functional improvement according to the MAYO questionnaire. 2. Comparison of the two groups in terms of pain severity. 3. Comparison of the two groups in terms of wrist range of motion in flexion and extension. 4. Comparison of the two groups in terms of fracture union rate. 5. Comparison of the two groups in terms of the scapholunate angle on lateral radiographs.

Design

randomized, single-blind, controlled clinical trial with parallel group conducted on 30 patients. Randomization was performed using SPSS software.

Settings and conduct

The study will be conducted at Besat Hospital in Hamadan. radiographs will be obtained at 1, 3, and 6 months after surgery, and the patients will be evaluated based on the study variables.

Participants/Inclusion and exclusion criteria

Inclusion criteria: provision of informed consent Exclusion criteria: Refusal to participate in the study, Loss to follow-up

Intervention groups

In the screw group (control), first, two 1-mm pins will be inserted under C-arm guidance from the volar to dorsal direction or vice versa, and from distal to proximal. Then, one screw will be inserted from distal to proximal. After that, the pins will be removed and a cast will be applied. In the screw-and-pin group (case), first, two pins will be inserted from distal to proximal and from volar to dorsal or vice versa toward the center of the scaphoid. Afterward, a screw will be inserted along the same axis, based on the size of the inserted and measured pin, and fixation will be achieved. The postoperative cast will be removed after approximately one month.

Main outcome variables

Functional improvement, pain severity, wrist range of motion, fracture union rate, and the scapholunate angle on lateral radiographs.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260423069141N1**
Registration date: **2026-07-19, 1405/04/28**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-19, 1405/04/28**
Update count: **0**

Registration date

2026-07-19, 1405/04/28

Registrant information

Name

Mohamad Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3326 4003

Email address

m.amini@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the results of scaphoid waist fracture fixation using screws and screws with pins in acute scaphoid waist fractures

Public title
Comparing scaphoid waist fracture fixation using screws and screws with pins

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed scaphoid waist fracture
Exclusion criteria:
Presence of an associated wrist fracture Chronic fracture Fracture associated with ligament injury and perilunate injury Need for open surgery (open surgical procedure) Presence of SNAC signs

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization will be used in this study. In this method, each patient will have an equal probability of being assigned to one of the two treatment groups, and patient allocation will be performed independently of the allocation of other participants. The unit of randomization in this study is individual randomization, meaning that each patient will be independently assigned to one of the two treatment groups. Stratified randomization will not be used in this study because the primary objective is to compare the overall outcomes of the two treatment methods, and no specific variable has been considered for stratification. The random allocation sequence will be generated using a random number table/statistical software. Initially, a random sequence for the entire sample size will be generated using statistical software (such as SPSS or Random Allocation Software), so that each patient will be randomly assigned to either the “screw fixation” group or the “screw plus pin fixation” group. The allocation result for each number will then be written on a separate sheet and placed inside an opaque envelope. The envelopes will be sequentially numbered. To prevent selection bias, the Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) method will be used for allocation concealment. The envelopes will be opaque and numbered in sequence. After patient enrollment and baseline data collection, the corresponding envelope will be opened by the researcher to determine the type of intervention. The individual responsible for generating the random allocation sequence will have no involvement in patient enrollment or outcome assessment.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the patients and the data analyst will be blinded to the type of intervention; however, blinding of the surgeon will not be feasible due to the nature of the surgical procedure. Patients will be informed that they may randomly receive one of the treatment methods, but they will ultimately remain unaware of the specific procedure performed. In addition, the statistician/data analyst will be blinded to group allocation. The treatment groups will be identified using specific codes (such as Group A and Group B), and the analyst will not have access to the actual type of interventions until completion of the statistical analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences

Street address
Shahid Fahmideh Blvd, Hamadan

City
Hamadan

Province
Hamadan

Postal code
6517838784

Approval date
2026-04-18, 1405/01/29

Ethics committee reference number
IR.UMSHA.REC.1405.015

Health conditions studied

1

Description of health condition studied
scaphoid waist fracture

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Improvement in wrist joint function
Timepoint
At the beginning of the study and at 1-, 3-, and 6-month follow-up periods after surgery.
Method of measurement
MAYO questionnaire

2

Description
Pain severity
Timepoint
At the beginning of the study and at 1-, 3-, and 6-month follow-up periods after surgery.
Method of measurement
Visual Analogue Scale

3

Description
Wrist range of motion in flexion and extension
Timepoint
At 3 and 6 months after surgery.
Method of measurement
Joint range of motion in different directions using a goniometer.

4

Description
Fracture union rate.
Timepoint
At 1, 3, and 6 months after surgery.
Method of measurement
Based on the presence of tenderness in the anatomical snuffbox and the complete crossing of bony trabeculae on all three radiographic views (posteroanterior, lateral, and scaphoid views).

5

Description
Scapholunate angle on lateral radiographs.
Timepoint
At 1, 3, and 6 months after surgery.
Method of measurement
The angle between the scaphoid axis (a line drawn along its longitudinal poles) and the lunate axis (a line perpendicular to the line connecting its proximal and distal ends) is measured. The normal range is 30–60 degrees.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A 3–5 mm incision will be made on the volar or dorsal side. First, two pins will be inserted from distal to proximal and from volar to dorsal, or vice versa, toward the center of the scaphoid. Then, a screw will be inserted along the same axis, corresponding to the length of the inserted and measured pin, and fixation will be achieved. The postoperative cast will be removed after approximately one month.
Category
Treatment - Surgery

2

Description
Control group: A 3–5 mm incision will be made on the volar or dorsal side. First, two 1-mm pins will be inserted under C-arm guidance from the volar to dorsal direction or vice versa, and from distal to proximal. Then, one screw will be inserted from distal to proximal. After that, the pins will be removed and a cast will be applied. The cast will be removed one month after surgery.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Rohollah Abasi
Street address
Shahid Beheshti Blvd, Hamadan, Iran
City
Hamadan
Province
Hamadan
Postal code
6515737461
Phone
+98 81 3264 0030
Fax
Email
besat@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Alireza Soltanian
Street address

Hamadan, Pajoohesh Crossroad, Shahid Fahmideh Blvd

City
Hamadan

Province
Hamadan

Postal code
6517838784

Phone
+98 81 3131 4058

Email
Fanavari@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Hamedan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Mohamad Amini

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Shahid Beheshti Blvd, Hamadan

City
Hamadan

Province
Hamadan

Postal code
6515737461

Phone
+98 81 3824 1515

Email
M.AMINI@UMSHA.AC.IR

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Mohamad Amini

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Shahid Beheshti Blvd, Hamadan

City
Hamadan

Province
Hamadan

Postal code
6515737461

Phone
+98 81 3264 0020

Email
M.AMINI@UMSHA.AC.IR

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Mohamad Amini

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Shahid Beheshti Blvd, Hamadan

City
Hamadan

Province
Hamadan

Postal code
6515737461

Phone
+98 81 3264 0020

Email
M.AMINI@UMSHA.AC.IR

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available